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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/080,504	02/22/2002	Olaf Reinhold	030903.0004.UTL	8672

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EXAMINER	
LEWIS, AARON J	

ART UNIT	PAPER NUMBER
3761	

DATE MAILED: 10/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/080,504	REINHOLD ET AL.	
	Examiner	Art Unit	
	AARON J. LEWIS	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 February 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-3,8,10-14,18,19,21-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Stimpson et al. ('416).

As to claim 1, Stimpson et al. disclose a device for delivering an aerosolized compound, the device comprising: a reservoir (L) that stores the compound; a system comprising an entry port (68) and an element (62) to generate particles of a desired size for ejection from an ejection head of the element (fig.8a), wherein said particles comprise a compound (col.3, lines 23-28), and wherein said system is fluidly connected to a reservoir; and a housing (43,44) comprising an inlet (68) and an outlet (81) between which is formed an airflow path and in which at least the ejection head is disposed in the air flow path (see arrows indicating air flow path in fig.7a) downstream of the inlet and upstream from the outlet, wherein the housing provides for a substantially unobstructed airflow between the ejection head and the outlet when air traverses the airflow path from the inlet to the outlet.

As to claims 2 and 3, the compound (col.3, lines 23-28) is a pharmaceutical compound and is stored in the reservoir in a liquid formulation (L).

As to claim 8, the reservoir and particle generating system (50) of Stimpson et al. are disposed within the housing (43,44).

As to claim 10, the reservoir of Stimpson et al. is illustrated as being detachable (figs.3,3a,6,7) from the housing.

As to claim 11, the reservoir and particle generating system are integrated into a single detachable unit (fig.8).

As to claims 12-14, the particle generation system (62) of Stimpson et al. (col.5, lines 28-57) is an electronic piezoelectric ejection device which also uses heat to generate particles ejected from its head.

As to claim 18, the unobstructed airflow in Stimpson et al. is illustrated as being substantially laminar (see arrows indicating airflow through mouthpiece 24) prior to exiting the housing outlet (fig.7a).

As to claim 19, the substantially unobstructed airflow in Stimpson et al. (e.g. fig.7a) comprises a substantially homogeneous mixture of the ejected compound and air (from inlet 68) in the airflow prior to exiting the housing outlet (81).

Claims 21 and 23 are substantially equivalent in scope to claim 1 and are included in Stimpson et al. for the reasons set forth above with respect to claim 1. Additionally, Stimpson et al. illustrate air flow with arrows (70) in fig.7a. The airflow illustrated by these arrows inherently indicates substantially unobstructed airflow as well as substantially non-turbulent airflow when air traverses the airflow path from the inlet to the outlet.

As to claim 22, Stimpson et al. (fig.7a) illustrates air being drawn from inlet (68) to outlet (81).

As to claim 24, the airflow in Stimpson et al. (fig.7a) between the ejection head (62) and outlet (81) is illustrated as being substantially laminar (see airflow arrows in mouthpiece 24).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 4-7,15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stimpson et al. ('416) in view of Michaels et al. ('854).

The difference between Stimpson et al. and claim 4 is the particular type of drug being delivered.

Michaels et al., in a device for delivering an aerosolized compound, teach the use of a variety of drugs including proteins, hormones and drugs which fall into the category of small molecules (col.2, lines 11-20 and col.6, lines 5-13) for the purpose of treating a variety of ailments.

It would have been obvious to delivery a variety of drugs using the device of Stimpson et al. including proteins, hormones and small molecules because it would have provided a means for treating a variety of respiratory ailments as taught by Michaels et al..

Claims 5-7 are included in Stimpson et al. as modified by Michaels et al. for the reasons set forth above with respect to claim 4. As to the recited gene delivery vehicle in claim 7, it is submitted that nebulizer of Stimpson et al. alone and as modified by Michaels et al. is fully capable of nebulizing liquid medicaments which are aerosolizable and inhalable including a medicament which is a gene delivery vehicle.

As to claims 15-17, the particles generated by Michaels et al. are of a size that allows the particles to transit to and be deposited in alveoli (col.4, lines 23-26). The particular particle diameter is dependent upon the selected pore diameter of a given porous body (col.4, line 4); consequently, the particle diameter can be arrived at through mere routine obvious experimentation and observation. The determining factor in the selection of a given porous body having a particular pore size as taught by Michaels et al. is the intended depth of deposition within a patient's respiratory system.

5. Claims 9 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stimpson et al. ('416).

As to claim 9, the shape of the reservoir of Stimpson et al. includes curved surfaces which conduct airflow therethrough in an efficient manner; consequently, these curved surfaces are readable upon an aerodynamic shape.

As to claim 20, the inner suface of the housing (50) of Stimpson et al. (fig.7a) proximal to the ejection head (62) and extending to the outlet (81) is contoured (see curved inner surface of housing 50 in fig.7a) to minimize turbulence.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 20 recites the limitation "...the inner surface..." in line 1. There is insufficient antecedent basis for this limitation in the claim.

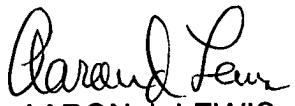
Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The balance of the art is cited to show relevant devices for delivering aerosolized medicament.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARON J. LEWIS whose telephone number is (703) 308-0716. The examiner can normally be reached on 9:30AM-6:00PM M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, WEILUN LO can be reached on (703) 308-1957. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



AARON J. LEWIS
Primary Examiner
Art Unit 3761

Aaron J. Lewis
September 28, 2003